## This Page Is Inserted by IFW Operations and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

THIS PAGE BLANK (USPTO)

## XP 002152846

AN - 1996-263781 [27]

AP - JP19940270731 19941007

**CPY - AMAN** 

- SHIE

DC - A11 A14 A96 B07

DR - 0460-S 0460-U 0479-S 0479-U 1126-S 1126-U

FS - CPI

IC - A61K9/36; A61K9/50; A61K47/26; A61K47/32; A61K47/38

MC - A03-A01 A11-B05 A12-V01 A12-W05 B04-C02A2 B04-C02A3 B04-C03B B04-L05B B04-L05C B12-M11D B12-M11K

M1 - [01] M423 M424 M430 M740 M781 M782 M903 Q120 R032 R038 V712 V713 V735

- [02] M423 M424 M430 M740 M782 M903 Q120 R032 R038 V802 V810

- [03] H5 H521 H8 J0 J011 J1 J171 M210 M212 M272 M280 M281 M311 M321 M342 M349 M381 M391 M423 M424 M430 M740 M782 M903 M904 Q120 R032 R038 V712; R16919-M
- [04] H4 H401 H481 H5 H521 H581 H8 J0 J011 J012 J1 J171 J2 J221 M210 M211 M262 M272 M280 M281 M312 M313 M320 M321 M332 M342 M381 M382 M391 M423 M424 M430 M740 M782 M903 M904 Q120 R032 R038 V712; R16922-M
- [05] H7 H714 H721 J0 J011 J2 J271 M210 M212 M262 M272 M281 M320 M416 M423 M424 M430 M740 M782 M903 M904 M910 Q120 R032 R038 V743; R01126-M R01126-Q; 1126-S 1126-U
- [06] H7 H721 J0 J011 J1 J171 M210 M213 M232 M262 M281 M320 M416 M423 M424 M430 M740 M782 M903 M904 M910 Q120 R032 R038 V743; R00460-M R00460-Q; 0460-S 0460-U
- [07] H7 H721 J0 J011 J2 J271 M210 M211 M213 M232 M262 M272 M281 M320 M416 M423 M424 M430 M740 M782 M903 M904 M910 Q120 R032 R038 V743; R00479-M R00479-Q; 0479-S 0479-U

M6 - [08] M903 Q120 R032 R038 R120 R307

PA - (AMAN) AMANO PHARM KK

- (SHIE ) SHINETSU CHEM IND CO LTD

PN - JP8109126 A 19960430 DW199627 A61K9/50 007pp

PR - JP19940270731 19941007

XA - C1996-083700

XIC - A61K-009/36 ; A61K-009/50 ; A61K-047/26 ; A61K-047/32 ; A61K-047/38

AB - J08109126 Granules, partic. spheres of 1.0 mm diameter or less, having saccharide cores carrying effective ingredient(s), esp. an acid labile enzymes, coated with, partic. 15-50 wt. % of enteric coating base, at least 2 layers with softening temp. difference(s) of 50 deg. C or over such that at least one layer is an enteric coating layer. Layer(s) partic. prepd. by aq. coating, composed of one or more hydroxymethylcellulose phthalate (HPMCP), hydroxypropylmethylcellulose acetate succinate (HPMCAS), cellulose acetate phthalate (CAP), carboxymethylcellulose (CMEC), methacrylic acid-ethyl acrylate copolymer and methacrylic acid-methyl methacrylate copolymer, and 1-25 wt. % of the other enteric coating layer. Also claimed are tablets prepd. from the above granules togeth r with e.g. fillers, disintegrators, binders and lubricants.

- ADVANTAGE Granules durable to tabletting pressure makes combinations with acid labile components (e.g. enzymes) possible.
- In an example, in a centrifugal coating apparatus, 1 kg of saccharide particles were placed and 4 % aq. soln. of 400 g of



hydroxypropylcellulose was sprayed together with a mixt. of 1 kg of pancr atin and 500 g of corn starch to give 2,250 g of the core particles. In a fluid bed coating apparatus, 1.5 kg of the core particles, 45 g of hydroxypropylmethylcellulose (HPMC) and 225 g of talc dispersed in 1,230 g of purified water was sprayed at 80 deg. C and a rate of 25 g/min. to give 1,730 g of granules coated with water soluble film. In the coating apparatus, 1.5 kg of the coated granules was spray coated with a dispersed mixt. of 525 g of HPMCAS, 147 g of Et citrate, 157.5 g of talc in 4,420.5 g of purified water at 80 deg. C and rate of 60 g/min. to give 2,240 g of enteric coated granules. The granules, 1.5 kg, were further coated with a dispersed mixt. of 45 g each of HPMC and talc in 1,410 g of purified water at a temp. of 80 deg. C and rate of 30 g/min. to give 1,570 g of the granules.(Dwg.0/0)

CN - R00460-M R00460-Q R00479-M R00479-Q R01126-M R01126-Q R16919-M R16922-M

DRL - 0460-S 0460-U 0479-S 0479-U 1126-S 1126-U

IW - SHOCK ENTERAL COATING GRANULE TABLET COMPRISE SPHERE SACCHARIDE CORE CARRY ACID LABILE ENZYME

IKW - SHOCK ENTERAL COATING GRANULE TABLET COMPRISE SPHERE SACCHARIDE CORE CARRY ACID LABILE ENZYME

NC - 001

OPD - 1994-10-07

ORD - 1996-04-30

PAW - (AMAN ) AMANO PHARM KK

- (SHIE ) SHINETSU CHEM IND CO LTD
- TI Shockproof enteric coating granules and tablets comprises spheres with saccharide cores carrying e.g. acid labile enzyme(s)
- A01 [001] 018; G3689 G3678 G3634 D01 D03 D11 D10 D23 D22 D42 D76 F24 F34 H0293 P0599 G3623 D31 D50 D60 F35-R; R16917 G3645 G3634 G3623 D01 D03 D10 D11 D18 D19 D22 D23 D42 D50 D63 E19 F24 F34 F41 P0599 H0293; S9999 S1616 S1605; S9999 S1014-R;
  - [002] 018 ; G3690 G3634 G3623 P0599 D01 D03 D11 D23 D42 D63 D76 F24 F34 H0293 D19 D18 D50 F26-R E19 E00; S9999 S1014-R; S9999 S1616
  - [003] 018; G3690 G3634 G3623 P0599 D01 D03 D11 D23 D42 D63 D76 F24 F34 H0293 D50 F26-R E11 E00; S9999 S1616 S1605; S9999 S1014-R;
  - [004] 018; R00460 G0306 G0271 G0260 G0022 D01 D12 D10 D26 D51 D53 D58 D60 D84 F36 F35; R01126 G0340 G0339 G0260 G0022 D01 D11 D10 D12 D26 D51 D53 D58 D63 D85 F41 F89; H0022 H0011; S9999 S1014-R; S9999 S1616 S1605; P0088;
- [005] 018; R00460 G0306 G0271 G0260 G0022 D01 D12 D10 D26 D51 D53 D58 D60 D84 F36 F35; R00479 G0384 G0339 G0260 G0022 D01 D11 D10 D12 D26 D51 D53 D58 D63 D85 F41 F89; H0022 H0011; S9999 S1014-R; S9999 S1616 S1605; P0088;
- [006] 018; ND01; Q9999 Q7114-R; Q9999 Q8037 Q7987; N9999 N7147 N7034 N7023; N9999 N7067 N7034 N7023; K9701 K9676; K9574 K9483; B9999 B4159 B4091 B3838 B3747; B9999 B5629 B5572; K9745-R; K9972
- [007] 018; K9449; N9999 N7090 N7034 N7023; B9999 B5447 B5414 B5403 B5276;
- [008] 018; G3190 R01541 D00 F80 O- 6A Mg 2A Si 4A; A999 A237; A999 A771;
- [009] 018; A999 A340-R; A999 A771;

- [010] 018; D01 D11 D10 D50 D63 D92 F27 F26 F91 F41 E35 E30; A999 A340-R;
- A02 [001] 018; R03005 G3678 G3634 D01 D03 D11 D10 D23 D22 D31 D42 D50 D76 D93 F24 F29 F26 F34 H0293 P0599 G3623; S9999 S1616 S1605;
  - [002] 018; ND01; Q9999 Q7114-R; Q9999 Q8037 Q7987; N9999 N7147 N7034 N7023; N9999 N7067 N7034 N7023; K9701 K9676; K9574 K9483; B9999 B4159 B4091 B3838 B3747; B9999 B5629 B5572; K9745-R; K9972;
  - [003] 018; N9999 N7067 N7034 N7023; Q9999 Q6791; N9999 N7090 N7034 N7023; B9999 B5447 B5414 B5403 B5276;
  - [004] 018; R01740 G2335 D00 F20 H- O- 6A; A999 A475;
- A03 [001] 018; R06563 G3678 G3634 G3623 P0599 D01 D03 D11 D10 D23 D22 D31 D42 D50 F24 F26 F34 H0293; S9999 S1025 S1014;
  - [002] 018; ND01; Q9999 Q7114-R; Q9999 Q8037 Q7987; N9999 N7147 N7034 N7023; N9999 N7067 N7034 N7023; K9701 K9676; K9574 K9483; B9999 B4159 B4091 B3838 B3747; B9999 B5629 B5572; K9745-R; K9972
  - [003] 018; B9999 B3521-R B3510 B3372; N9999 N7090 N7034 N7023; B9999 B5447 B5414 B5403 B5276; K9449; K9712 K9676;
  - [004] 018; G3190 R01541 D00 F80 O- 6A Mg 2A Si 4A; A999 A237; A999 A771;
  - [005] 018; A999 A340-R; A999 A771;
- A04 [001] 018; R01863-R D01 D11 D10 D23 D22 D31 D42 D50 D76 D86 F24 F29 F26 F34 H0293 P0599 G3623;
  - [002] 018; ND01; Q9999 Q7114-R; Q9999 Q8037 Q7987; N9999 N7147 N7034 N7023; N9999 N7067 N7034 N7023; K9701 K9676; K9574 K9483; B9999 B4159 B4091 B3838 B3747; B9999 B5629 B5572; K9745-R; K9972;
  - [003] 018; N9999 N7067 N7034 N7023; Q9999 Q6791; N9999 N7090 N7034 N7023; B9999 B5447 B5414 B5403 B5276;

THIS PAGE BLANK (USPTO)



AN - 1995-019176 [03]

AP - JP19930263814 19931021

**CPY - TERU** 

DC - B02

FS - CPI

IC - A01N47/28; A01N47/30; A61K31/34; C07D317/58; C07D319/18; C07D405/12

MC - B06-A02 B14-A01 B14-E08

M2 - [01] D022 D140 D150 F010 F011 F012 F014 F021 F431 F433 G012 G100 H103 H181 H201 H5 H521 H541 H8 J0 J011 J3 J371 K0 L4 L420 L941 M123 M126 M132 M210 M211 M212 M213 M214 M215 M216 M220 M221 M222 M223 M224 M225 M226 M231 M232 M233 M240 M273 M280 M281 M282 M311 M312 M313 M314 M315 M321 M322 M323 M332 M342 M349 M373 M381 M383 M391 M392 M412 M431 M511 M520 M521 M522 M530 M531 M540 M782 M903 M904 P220 P738 R038; 01662; 9503-17201-M

M6 - [02] M903 P220 P738 R038 R111 R120 R280 R307 R313

PA - (TERU) TERUMO CORP

PN - JP6305960 A 19941101 DW199503 A61K31/34 018pp

PR - JP19930039042 19930226

XA - C1995-008681

XIC - A01N-047/28; A01N-047/30; A61K-031/34; C07D-317/58; C07D-319/18; C07D-405/12

AB - J06305960 Solid oral preparations comprises a thiourea deriv. of formula (I) and an acidic substance that shows pH 6.5 or lower when dissolved in water, separated by a micro-partition.

- In (I), R1 and R2 = lower alkyl; R1 + R2 = -(CH2)x-CHR3-(CH2)y-; R3 = H or lower alkyl; X and Y = 0-2; A = CH=CH- or -CH=N-; L = 1 or 2; m = 0-2; n = 1-5.

- The partition may be formed by powder coating with w.g. lactose, starch, talc, titanium oxide, refined sugar, glucose, calcium phosphate, mannitol, xylitol, sorbitol, calcium carbonate, crystalline cellulose or by film coating with et.g. hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose phthalate, methylcellulose, polyvinyl alcohol, polyvinyl propylmethylcellulose phthalate, methylcellulose, polyvinyl alcohol, polyvinyl pyrrolidone, carboxymethylethylcellulose, ethylcellulose, acetate phthalate cellulose, aminoalkyl methylacrylate, methacrylate copolymer or shellac.
- USE/ADVANTAGE (I) have antimicrobial action against Helicobacter pylori and are useful as antiulcer agents. The prepns. are stable for long-term preservation and readily release (I) when dissolved in water. - (Dwg.0/0)

CN - 9503-17201-M

IW - SOLID ORAL PREPARATION CONTAIN THIOUREA DERIVATIVE ANTIMICROBIAL ACTIVE IKW - SOLID ORAL PREPARATION CONTAIN THIOUREA DERIVATIVE ANTIMICROBIAL ACTIVE

OPD - 1993-02-26

ORD - 1994-11-01

PAW - (TERU ) TERUMO CORP

RRL - 01662

TI - Solid oral preparations contg. thiourea derivs. - have antimicrobial

activity against e.g Helicobacter pylori